Amendments to the Specification

Please amend the two paragraphs starting at line 3 on page 3 as follows:

It is, of course, apparent that over-the-wire catheters cannot be positioned adjacent the stenosis until the ~~guidewire~~ guide wire has been advanced across the stenosed area. In those instances where the artery is ~~the~~ occluded, the surgeon may have greater difficulty in guiding the guide wire through the occluded area. For example, the occlusion may contain complex structures which ~~to~~ divert the steering end of the guidewire. Thus, without some type of guidance system, the ~~guidewire~~ guide wire might undesirably impinge on and possibly perforate or otherwise damage the artery wall.

In light of the foregoing, there has been a long-felt need to provide a reliable guidance system for guiding a catheter through the occlusion. One prior art guidance system which has been used in conjunction with coronary catheterization involves biplane fluoroscopy, wherein the surgeon observes two flat, real-time ~~x-ray~~ X-ray images acquired from different angles. However, biplane fluoroscopy has been proven to be somewhat costly, unreliable and slow.

Amendments to the Specification continued

Please amend the paragraph starting at line 3 on page 5 as follows:

Another promising technology for use in catheter guidance systems is Optical Coherence Reflectometry (OCR). The basic concepts of this technology have been well documented (see for example an article by Mandel L. Wolf entitled "Optical Coherence and Quantum Optics" published in the Cambridge University Press (1995)). In the practice of the OCR technology, a light source is divided into two beams, a reference arm and a sample arm. The light in the reference arm is reflected at a determinable path length. Light in the sample is also reflected or scattered by the material present in the sample. The reflections and backscattered light are combined at an optic coupler, and if the path lengths of the two arms are within the coherence length of the light, the light will recorrelate or interfere with one another. The detector measures the interference intensity. Since the reference path length is known and adjustable, the intensity profile of scattered light from a sample can be determined as a function of the reference arm path length.

Please amend the paragraph starting at line 3 on page 7 as follows:

A form of prior art optical fiber guide wire similar to the "SAFE-STEER" ~~guidewire~~ guide wire is illustrated and described in an article entitled "Lasers In Surgery: Advanced Characterization Therapeutics, and Systems XI" (~~Proceedings~~

Amendments to the Specification continued

~~of the Society of Photo-Optical Instrumentation Engineers,~~ *Proceedings of The Society of Photo-Optical Instrumentation Engineers*, Volume 4244).

Please amend the paragraph starting at line 15 on page 7 as follows:

Still another commercially available, prior art catheter system using radio frequency technology is sold by IntraLuminal Therapeutics of Carlsbad, California under the name and style "SAFE-CROSS." The Safe-Cross system was developed to effectively cross and recanalize total occlusions and, according to the manufacturer, comprises a marriage of the OCR technology and controlled Radio Frequency (RF) energy to facilitate guidance through the occlusion.

Please amend the paragraph starting at line 16 on page 9 as follows:

Figure 5 is a greatly enlarged, cross-sectional view of the portion of the system designated as "5" in figure ~~1~~ 4.

Please amend the paragraph starting at line 14 on page 10 as follows:

Referring to the drawings and particularly to figures 1 through 3, one form of the ~~intervascular~~ intravascular catheter system of the invention is there shown and generally designated by the numeral 14. The catheter system here comprises a

Amendments to the Specification continued

catheter 16 having an outer sidewall 18, a proximal end 20 and distal end 22. As ~~been~~ can be seen by referring to figures 2 and 3, catheter 16 is provided with a first passageway 24 (figure 2) having a diameter of about 0.035 inches, a proximal end 26 and a distal end 28. Catheter 16 is preferably formed of a biocompatible and hydrophilic compatible material, such as a lubricous polyimide or polyethylene.

Please amend the paragraph starting at line 19 on page 11 as follows:

Also comprising a part of the ~~intervascular~~ intravascular catheter system of the invention are electronic means which are operably associated with optical fiber 38. These electronic means, which are generally identified in figure 1 by the numeral 39, comprise ~~apart~~ a part of the guidance means of the invention and uniquely provide guidance data to the user of the system to permit ~~to~~ the safe navigation of the catheter through the occlusion. The guidance means along with the optical fiber 38 form a part of the optical coherence reflectometry system (OCR) of the invention the character of which will presently be described.

Please amend the six paragraphs starting at line 19 on page 13 as follows:

Turning to figure 11, the optical coherence reflectometry system of the apparatus of the present invention comprises a low coherence light source 62 that

Amendments to the Specification continued

is input into a conventional fiber optic coupler 64[[,]] where the light is split and directed into a sample arm 66 and a reference arm 68. The previously identified optical fiber 38 is connected to sample arm 66 and extends into second passageway 32 of the catheter 16 in the manner shown in figure 1. The light in the reference arm 68 is reflected by reflecting means shown here as a mirror 70 at a determinable variable path length when the catheter system is in an initial position within the artery. Light in the sample arm 66 will be reflected or scattered by the material present in the occlusion within which the distal end of the catheter resides. The reflections and backscattered light are combined at a coupler 64 in a manner well understood by those skilled in the art. If the path lengths of the two arms are within the coherence length of the light, the light will re-correlate. A detector 72, which is operably[[,]] interconnected with the coupler, measures the interference intensity. Detector 72 is also of a character well known in the art. Since the reference path length is known and adjustable, the intensity profile of scattered light from a sample can be determined as a function of the reference arm path length. The scattered light is analyzed by electronic means[[,]] which here comprises the electronics 74 and a conventional computer system 76. The cooperative interaction of the electronics and the computer produces a signal tracing that is displayed and periodically updated on a suitable display 78. In a

Amendments to the Specification continued

manner well understood by those skilled in the art, the signal tracing is monitored by the computer through a series of algorithms to determine if the arterial wall is within the field of view. If the arterial wall is detected, a visual indication will appear on the display with the catheter assembly in its initial position within the artery. ~~if~~ If visual indication is not shown on the display, the ~~guidewire~~ guide wire can be further advanced a small distance into the ~~inclusion~~ occlusion. This done, the catheter is inserted over the ~~guidewire~~ guide wire to a position proximate the distal end of the ~~guidewire~~ guide wire and the monitor is viewed to verify that cautionary visual indication is still not shown on the display. If this is the case, the ~~guidewire~~ guide wire can be further inserted a small distance into the occlusion and the catheter then inserted over the guide wire a further distance. This procedure can be repeated until a visual indication appears on the display at which point the surgeon must take steps to reroute the steerable ~~guidewire~~ guide wire in ~~the~~ a direction away from the arterial wall. Unlike the prior art systems which use the optical fiber and its sheath as a guide wire, the apparatus of the present invention, which uniquely embodies a conventional steerable metal ~~guidewire~~ guide wire, such as ~~guidewire~~ guide wire 38, enables the surgeon to safely and expeditiously navigate through the occlusion with a minimum of a lost time and motion.

Amendments to the Specification continued

Turning next to figures 4 through 6, an alternate form of the ~~intervascular~~ intravascular catheter system ~~as~~ is there shown and generally designated by the numeral 84. Catheter system 84 is similar in many respects to that shown in figures 1 through 3 and like numerals are used in figures 4 through 6 to identify like components. As ~~been~~ can be seen in figures 4 and 5 catheter system 84 comprises a catheter 86 having an outer sidewall 88, a proximal end 90 and distal end 92. Catheter 86 is provided with a first passageway 94 having a proximal end 96 and a distal end 98. Catheter 86, like catheter 14, is preferably formed of a biocompatible and hydrophilic compatible material, such as a lubricous polyimide or polyethylene. The primary difference between catheter 86 and the previously described catheter 14 is that catheter 86 does not include an opening in its side wall for receiving the guide wire and additionally, as shown in figure 6, the passageway which receives the ~~guidewire~~ guide wire is axially aligned with the central axis of the catheter.

As indicated in figures 5 and 6, a conventional guide wire 30 is slideably movable within first passageway 94 between [[a]] first and second positions. Catheter 86 is also provided with a second passageway 102 which is radially spaced apart from first passageway 94. Second passageway 102 also has a proximal end 104 and a distal end 105. An optical fiber 38, which is carried within

Amendments to the Specification continued

second passageway 102 in the manner shown in figures 5 and 6, has a first end 107 and a second end 106, the second end being located proximate the distal end of second passageway 102. Also comprising a part of the ~~intervascular~~ intravascular catheter system of this latest form of the invention are instrument means of the character previously described that are operably associated with optical fiber 38 for providing, in the manner previously described, guidance data to the user of the system to permit [[to]] the safe navigation of the catheter through the occlusion. The instrument means, along with the optical fiber 38, forms a part of the optical coherence reflectometry system of the invention the character of which is illustrated in figure 11 of the drawings. The method of the invention using the alternate embodiment of the invention shown in figures 4 through 6 comprises the steps of first advancing the guidewire 30 through a vessel to a location proximate the occlusion. This done, the catheter 86 is interconnected with the ~~guidewire~~ guide wire by inserting the ~~guidewire~~ guide wire into the distal end of passageway 94. Following insertion of the ~~guidewire~~ guide wire into passageway 94, the catheter is controllably advanced over the ~~guidewire~~ guide wire to a location wherein the distal end of the catheter is also proximate the occlusion. The ~~guidewire~~ guide wire and the catheter are then incrementally inserted into the occlusion in the manner described in connection with the embodiment of the

invention shown in figures 1 through 3 with the surgeon periodically checking the display of the instrument means 39 to make certain that the catheter will not impinge on the artery wall.

Referring now to figures 7 through 9, still another form of the ~~intervascular~~ intravascular catheter system ~~as~~ is there shown and generally designated by the numeral 114. Catheter system 114 is similar in many respects to that shown in figures 4 through 6 and like numerals are used in figures 7 through 9 to identify like components. As has been seen in figures 7 and 8 catheter system 114 comprises a catheter 116 having an outer sidewall 118, a proximal end 120 and distal end 122. Catheter 116 is provided with a first passageway 124 having a diameter of approximately 0.035 inches, a proximal ~~and~~ end 126 and a distal ~~and~~ end 128. Catheter 116, like catheter 84, is preferably formed of a biocompatible and hydrophilic compatible material, such as a lubricous polyimide or polyethylene. The primary difference between catheter 116 and the previously described catheter 84 is that the passageway which receives the ~~guidewire~~ guide wire and the passageway that receives the optical fiber are both radially offset from the central axis of the catheter.

As indicated in figures 8 and 9, a conventional ~~guidewire~~ guide wire 30, which has a diameter of about 0.014 inches, is slideably movable within first

Amendments to the Specification continued

passageway 124 between [[a]] first and second positions. Catheter 116 is also provided with a second passageway 132 which is radially spaced apart from first passageway 124. Second passageway 132 also has a proximal end 134 and a distal end 135. An optical fiber 38, which is carried within second passageway 132 in the manner shown in figures 8 and 9, has a first end 136 and a second end 138, the second end being located proximate the distal end of second passageway 132. Also comprising a part of the ~~intervascular~~ intravascular catheter system of this latest form of the invention are instrument means of the character previously described that are operably associated with optical fiber 38 for providing, in the manner previously described, guidance data to the user of the system to permit to the safe navigation of the catheter through the occlusion. The instrument means, along with the optical fiber 38, forms a part of the optical coherence reflectometry system of the invention the character of which is illustrated in figure 11 of the drawings. The method of the invention using the alternate embodiment of the invention shown in figures 4 through 6 comprises the steps of first advancing the ~~guidewire~~ guide wire 30 through a vessel to a location proximate the occlusion. This done, the catheter 116 is interconnected with the ~~guidewire~~ guide wire by inserting the ~~guidewire~~ guide wire into the distal end of passageway 124. Following insertion of the ~~guidewire~~ guide wire into passageway 124, the catheter

is controllably advanced over the ~~guidewire~~ guide wire to a location wherein the distal end of the catheter is also proximate the occlusion. The ~~guidewire~~ guide wire and the catheter are then incrementally inserted into the occlusion in the manner described in connection with the embodiment of the invention shown in figures 4 through 6 with the surgeon periodically checking the display of the instrument means 39 to make certain that the catheter will not impinge on the artery wall.

Referring next to figures 12, 13 and 14 still another form of the ~~intervascular~~ intravascular catheter system of the invention is there shown and generally designated by the numeral 134. This catheter system is similar to that shown in figures 1 through 3 and like numbers are used in figures 12 through 14 to identify like components. The primary difference between system 134 and the earlier described embodiments of the invention resides in the fact that the guidance means for guiding the guide wire comprises a marriage of the previously described OCR technology and controlled radio frequency energy.

Please amend the two paragraphs starting at line 10 on page 20 as follows:

Catheter 16 is also provided with a second passageway 32 that is radially spaced apart from first passageway 24. Second passageway 32 also has a proximal

Amendments to the Specification continued

end 34 and a distal end 36. An energy transmission means, shown here as an energy conduit 136 is carried within second passageway 32. As indicated in figures 13 and 14, conduit 136 has a first end 138 and a second end 140, the second end being located adjacent the tip of the catheter and proximate the distal end 36 of second passageway 32. Energy conduit 136, which is of a character well known to those skilled in the art, can be of various sizes, but for present application preferably has a diameter [[of]] on the order of 0.0065 inches. Advantageously, energy conduit 136 can be used to penetrate and cross a total occlusion when such an occlusion is encountered.

Also comprising a part of the ~~intervascular~~ intravascular catheter system of the invention are electronic means, which are operably associated with conduit 136. These electronic means, which are generally identified in figure 12 by the numeral 142, provide guidance data to the user of the system to permit [[to]] the safe navigation of the catheter through the occlusion. A system suitable for use in this latest embodiment of the invention is commercially available from IntraLuminal Therapeutics, Inc. of Carlsbad, California under the name and style "SAFE CROSS." The details of construction and operation of this RF system are available from this company.